Potential Role of IP Law & Policy in Achieving Global Health Goals

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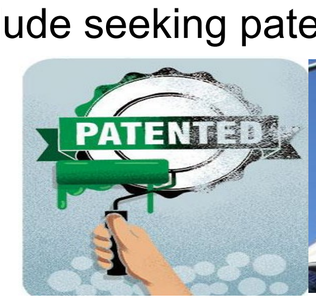
Background

Right to health is globally recognized as a basic human right. Both drug "innovation" and "access" are crucial for achieving the 2030 Agenda's goal of improving the health and well-being of all people at all ages (SDG3). Good health is also a prerequisite for achieving some other SDGs like "eradication of poverty and hunger" (SDG1&2). There is a two-way relationship between poverty and ill health as poverty contributes to disease while disease also contributes to poverty. The current innovation system has problems which lead to both "innovation" and "access" failures in the pharma sector. This study highlights one of these problems: Evergreening of drug patents.

Evergreening of Drug Patents

Brand name pharmaceutical companies use different risk-averse and less-costly evergreening tactics to extend their exclusive rights beyond 20 years patent term without making any genuine contribution to the progress of science and technology. These tactics include seeking patents for:

- new formulations;
- new combinations;
- new use of a known drug;
- new dosage forms.



Evergreening of drug patents has a two-fold negative impact.

- **Innovation Failures:** Drug companies divert their attention to incremental innovations. The National Institute of Health Care Management (NIHCM) found that only 15% of new drugs are highly innovative.
- **Access Failures:** High cost of drugs because of delayed generic competition.

Patent Litigation

Patent litigation is not a practically viable option to fix the problem of evergreening because:

- Patent litigation is notoriously risky, costly, lengthy, and cumbersome.
- The presumption of validity of granted patents favors the patentee in litigation.

Approach at International Level

- Instead of allowing powerful countries to dictate TRIPS plus IP standards through FTAs, developing countries need to collectively press for reinvigorating multilateral forums like the WTO & WIPO. FTAs are pro-profit and pro-evergreening. Art. 18.37(2) of the TPP specifically protects evergreening.
- The global community needs to honor the commitment to health as a basic human right and needs to collectively address drug access and innovation failures.

Research Questions

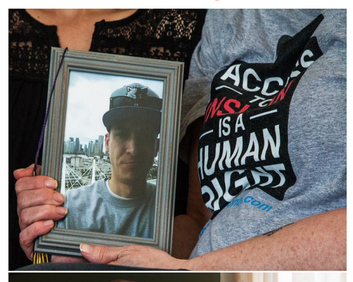
To what extent can the current innovation system help in achieving the UN's 2030 Agenda's Global Health Goals? How the practice of "Evergreening of drug patents" leads to "innovation" and "access" failures in the pharma sector? What policy options are available at the national level to curtail evergreening? What steps can be taken at the international level to harmonize innovation policy in the pharma sector with the UN's health-related SDGs?

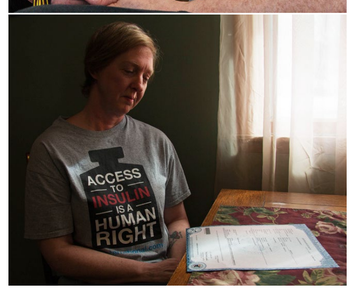
Methodology

This study uses literature review and qualitative empirical research methods.

Evergreening and SDGs 1,2&3

Access failures caused by evergreening of drug patents have serious implications for SDGs 1,2&3. 85% of the world's population lives in low and middle-income countries. 90% of the population in these countries makes out-of-packet payments for drugs. Ill health in these countries leads to poverty and hunger.





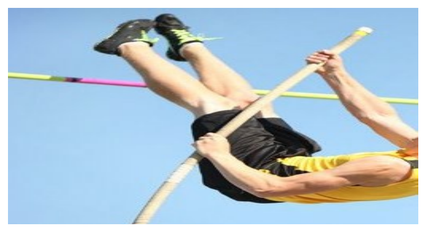
Evergreening is a killer even in the US

Alec, a diabetes patient in the US, turned 26 on May 20, 2018 and aged off his mother's insurance plan. Now, Insulin supplies would cost him $1300 a month. He died in less than one month. Insulin was discovered in 1921.Evergreening has still kept cheaper generic versions of Insulin out of the market.

India's Unique Approach

India combined two distinct TRIPS flexibilities to curtail evergreening of drug patents.

- India used TRIPS flexibility (under Art.27.1) to define patentability criteria and raised the threshold standard for patentability u/s 3(d) of the Patents Act.
- India used another TRIPS flexibility (under Art.41.2) and provided both pre-grant and post-grant patent opposition procedure to afford third parties an opportunity to challenge the validity of patents within the Patent Office in an affordable, feasible, and time-efficient manner.
- India linked s 3(d) with its opposition model. In India, in 87% cases, drug patents are opposed u/s 25(1)(f):"not an invention within the meaning of this Act". It invokes applicability of s 3(d) which provides a notable exception to patentability in India.



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